REMARKS

The pending Office Action addresses and rejects claims 1-26 and 29-63. Applicants respectfully request reconsideration and allowance based on the remarks submitted herewith.

Amendments to the Claims

Applicants amend claim 1 to remove the recitation "said proximal main member having a distally extending threaded recess in a proximal surface thereof." As previously discussed with the Examiner, this recitation was inadvertently included in the response filed on May 30, 2007. Applicants note that claim 1 was not amended in that response, but this recitation was inadvertently added by way of a typographical error. Applicants also amend claim 1 to recite that the expander pin is sized to expand the expandable body laterally when the expander pin is driven into the expandable body while the proximal main member and distal tip member are threadedly engaged. Support for this recitation can be found throughout the specification and drawings, for example at paragraph [0080] and FIGS. 21-30 and 50-53 of the published application. Further, Applicants delete the recited tissue attachment member from claim 1. Applicants amend claims 5 and 8 to introduce the tissue attachment member as a further component of the recited apparatus. Still further, Applicants amend claim 1 to recite that the expandable body is configured to attach to the bone rather than recite that it is attached to the bone. No new matter is added.

Applicants amend claim 29 to recite that the expandable body includes a distal tip member and a proximal main member that are separable from one another. Applicants also amend claim 29 to recite an installation tool that includes a shaft slidingly received in said bore of said expandable body and a bore of said expander pin and having a distal end and a proximal end, the distal end extending distally beyond a distal end of the distal tip member of the expandable body. Further, Applicants amend claim 29 to recite that the expander pin is driven distally into the expandable body. Support for these recitations can be found throughout the specification and drawings, for example at paragraphs [0058], [0060], [0064], [0072], and [0078] and FIGS. 1-9, 21-30, 39, 43, 44, 46, 50-53, and 57 of the published application. Applicants also delete the recited tissue attachment member from claim 29. Applicants amend claims 33 and 36 to introduce the tissue attachment member as a further component of the recited

apparatus. Still further, Applicants amend claim 29 to recite that the expandable body is configured to attach to the bone rather than recite that it is attached to the bone. Applicants cancel claims 41, 49, and 53 and fix dependencies in claims 42-45, 50-52, and 54. No new matter is added.

Objections to Priority

The Examiner objects to Applicants' priority claim for claims 1-26 and 60-63 for failing to comply with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120. The Examiner argues that the recitation "said proximal main member having a distally extending threaded recess in a proximal surface thereof" is not disclosed in the prior-filed application, U.S. Application Serial No. 09/714,549, which is now U.S. Patent No. 6,733,506 of McDevitt et al. ("the '506 patent"). As a result, the Examiner argues that the claim of priority is improper.

At least because the recitation in question has been deleted from claim 1, this objection is moot. Each of the recitations recited in the amended claims is disclosed by the '506 patent. Accordingly, the appropriate priority date for each claim of the present application, including claims 1-26 and 60-63, is at least as early as November 16, 2000, which is the filing date of the '506 patent.

Rejections Pursuant to 35 U.S.C. § 112

The Examiner rejects claims 1-26 and 60-63 pursuant to 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner argues that the recitation "said proximal main member having a distally extending threaded recess in a proximal surface thereof" is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention.

At least because the recitation in question has been deleted from claim 1, this objection is moot. Each of the recitations recited in claims 1-26 and 60-63 are adequately disclosed in the specification and drawings.

Rejections Pursuant to 35 U.S.C. § 102

U.S. Patent No. 5,935,129 of McDevitt et al.

The Examiner rejects claims 29-37, 40, 41, 43, 45-50, and 52-58 as being anticipated by U.S. Patent No. 5,935,129 of McDevitt et al. ("McDevitt '129"). Claim 29 is independent, claims 30-37, 40, 43, 45-48, 50, 52, and 54-58 depend therefrom, and claims 41, 49, and 53 have been canceled.

Claim 29 recites an apparatus for attaching tissue to bone that includes an expandable body configured to expand into bone, an expander pin, and an installation tool. The expandable body defines a bore and includes a distal tip member and a proximal main member that are separable from one another. The expander pin includes a shaft that is sized to be received in the bore of the expandable body and to expand the expandable body laterally when the expander pin is driven into the expandable body. The installation tool includes a shaft that has a distal end and a proximal end. The distal end of the shaft of the installation tool extends distally beyond a distal end of the distal tip member of the expandable body. The apparatus is configured such that when the expander pin is driven distally into the expandable body, the expandable body is attached to the bone.

McDevitt '129 fails to anticipate claim 29 at least because it fails to disclose an apparatus having an expander pin that can be driven distally into the expandable body. The Examiner argues that the embodiment described and illustrated with respect to FIG. 1(b) of McDevitt '129 includes an installation tool as now recited in claim 29. In this embodiment, however, the alleged installation tool, shaft 2, is specifically designed to be pulled *proximally* toward the alleged expandable body, sleeve 4, to move the alleged expander pin, expander element 51, *proximally* toward and into the sleeve, thereby expanding the sleeve. (*See* col. 7, lines 9-56; emphasis added.) The expander element (51) is not configured to be driven *distally* into the sleeve (4) as required by claim 29. In fact, McDevitt '129 is specifically designed to avoid driving an expander pin, or an installation tool, in the distal direction. The disclosure of McDevitt '129 states that the advantages provided by its design:

> are in contradistinction to prior art anchors – particularly, those in which an expansion member (e.g., analogous to an insertion stem) is pushed into an expandable member (e.g., analogous to a sleeve) – wherein the expansion members' movement can cause longitudinal extension of the expandable member and wherein it is necessary for

> the surgeon to exert a downward force in order to insure that the expandable member remains in the bone hole during deployment.
>
> *Id.*

Thus, the apparatus of McDevitt '129 is not configured to operate in a manner in which the expander pin is *driven distally* into the expandable body. Rather, it is specifically designed to operate *in the complete opposite manner.*

Accordingly, claim 29, as well as claims 30-37, 40, 43, 45-48, 50, 52, and 54-58 which depend therefrom, distinguishes over McDevitt '129 and represents allowable subject matter.

U.S. Patent No. 6,332,778 of Choung

The Examiner rejects claims 29, 41, and 42 as being anticipated by U.S. Patent No. 6,332,778 of Choung ("Choung"). Claim 29 is independent, claim 42 depends therefrom, and claim 41 is canceled.

Claim 29 includes recitations directed to an installation tool that includes a shaft having a distal end and a proximal end that extends distally beyond a distal end of the distal tip member of the expandable body. Choung fails to disclose such an installation tool. Choung discloses a "desire[d] instrument" that the Examiner argues serves as an installation tool for rotating the alleged expander pin, screw 30. (*See* col. 5, lines 34-36.) The "desire[d] instrument" is received in a bore (Phillips-head screwdriver mating portion) of the screw (30). (*See* page 12, line 21 to page 13, line 3 of the Office Action dated September 17, 2009.) Thus, the "desire[d] instrument" does not and cannot extend distally beyond a distal end of the alleged expandable body of Choung – fixture body 10 and cap 50.

Accordingly, claim 29, as well as claim 42 which depends therefrom, distinguishes over Choung and represents allowable subject matter.

U.S. Patent No. 7,074,203 of Johanson et al.

The Examiner rejects claims 29, 56, and 59 as being anticipated by U.S. Patent No. 7,074,203 of Johanson et al. ("Johanson"). Claim 29 is independent and claims 56 and 59 depend therefrom.

Claim 29 recites an expandable body that includes a distal tip member and a proximal main member that are separable from one another. Claim 29 also recites an installation tool that includes a

shaft that extends distally beyond a distal end of the distal tip member of the expandable body. Johanson fails to disclose either of these recitations. There is no indication in the disclosure of Johanson that the alleged expandable body, expandable sleeve 4, is separable into two or more members such as a distal tip member and a proximal main member. In fact, Johanson teaches including a membrane on radial or longitudinal slots that run all or part-way along the expandable sleeve (4) to *guard against breakage of the expandable sleeve*. (*See* col. 4, lines 48-53; emphasis added.) Further, the plunger-like deployment device that is used to deploy the Johanson expandable sleeve (4) does not extend distally beyond a distal end of the expandable sleeve. Rather, a distal end of a rod (29) of the plunger-like deployment device is configured to engage a rivet (6) and push the rivet into the expandable sleeve (4) to expand the expandable sleeve. (*See* col. 6, lines 13-36 and FIGS. 6-12.) No component of Johanson extends beyond the distal tip of the expandable sleeve (4).

Accordingly, claim 29, as well as claims 56 and 59 which depend therefrom, distinguishes over Johanson and represents allowable subject matter.

U.S. Patent No. 6,641,596 of Lizardi

The Examiner rejects claims 29, 49, and 51 as being anticipated by U.S. Patent No. 6,641,596 of Lizardi ("Lizardi"). Claim 29 is independent, claim 51 depends therefrom, and claim 49 is canceled.

Claim 29 recites an installation tool that includes a shaft that extends distally beyond a distal end of the distal tip member of the expandable body. Lizardi fails to disclose such an installation tool. The alleged installation tool (200) of Lizardi is configured to threadedly mate with a tip (40) of a suture anchor (12), but is not configured to extend distally beyond the suture anchor. (*See* col. 5, line 66 to col. 6, line 11.) The alleged insertion tool (200) cannot extend beyond a distal end of the tip (40) of the suture anchor (12) because then it would interfere with a suture-thread engaging groove (42) of the tip, and thereby the entire operation of the system of Lizardi.

Accordingly, claim 29, as well as claim 51 which depends therefrom, distinguishes over Lizardi and represents allowable subject matter.

Applicants note that Lizardi is prior art under 35 U.S.C. § 102(e) because it was filed on October 18, 2000, and the present application claims priority to November 16, 2000. Lizardi and the present

application were, at the time the invention of the present application was made, commonly owned by Ethicon, Inc. of Somerville, New Jersey. The assignment of the '506 patent to Ethicon Inc., of which the present application is a continuation, is recorded with the United States Patent and Trademark Office at Reel 013883, Frame 0240. The assignment of Lizardi to Ethicon, Inc. is recorded with the United States Patent and Trademark Office at Reel 011752, Frame 0774. Thus, pursuant to 35 U.S.C. § 103(c)(1), Lizardi cannot be relied upon to reject any claims in the present application under 35 U.S.C. § 103(a).

Rejections Pursuant to 35 U.S.C. § 103(a)

Choung in view of U.S. Patent No. 6,319,252

The Examiner rejects claims 1-5, 7, 12-17, and 44 pursuant to 35 U.S.C. § 103(a) as being obvious over Choung in view of U.S. Patent No. 6,319,252 of McDevitt et al. ("McDevitt '252"). Claim 1 is independent and claims 2-5, 7, and 12-17 depend therefrom. Claim 44 depends from claim 29. The Examiner argues that Choung discloses the recited apparatus for attaching tissue to bone except a distal tip member being of a harder material than a proximal main member. The Examiner relies on McDevitt' 252 to remedy the deficiencies of Choung. Applicants disagree.

Claims 1-5, 7, and 12-17

Claim 1 recites an apparatus for attaching tissue to bone that includes an expandable body defining a bore and configured to expand into bone and an expander pin. The expandable body includes a distal tip member and a proximal main member, and the distal tip member is of a harder material than the proximal main member. The distal tip member includes a threaded recess in its proximal surface and the proximal main member has a distally extending threaded projection threadedly interengageable with the distal tip member recess. The expander pin includes a shaft that is sized to be received in the bore of the expandable body and to expand the expandable body laterally when the expander pin is driven into the expandable body while the proximal main member and distal tip member are threadedly engaged. The apparatus is configured such that when the expander pin is driven into the expandable body, the expandable body is attached to the bone.

Choung fails to teach or even suggest an expander pin sized to expand the expandable body laterally when the expander pin is drive into the expandable body *while the proximal main member and distal tip member are threadedly engaged.* The Examiner argues that the implant of Choung includes an expandable body comprising a proximal main member, fixture body 10, and a distal tip member, cap 50, that is configured to expand into bone by driving an expander pin, screw 30, into the expandable body. The implant of Choung, however, can only be expanded *after* the cap (50) is removed. (*See* col. 5, lines 18-41 and FIGS. 2 and 3.) In fact, Choung discloses that the cap (50) is removed even before the fixture body (10) is inserted into the socket, which is obviously before the implant is expanded. (*Id.* at lines 30-33.) Thus, the alleged expander pin of Choung is not sized to expand the expandable body laterally when the expander pin is driven into the expandable body *while the proximal main member and distal tip member are threadedly engaged.*

McDevitt '252 fails to remedy the deficiencies of Choung, at least because a person having ordinary skill in the art would not modify the teachings of Choung in view of McDevitt '252 to arrive at the present invention. In order to arrive at the present invention, a person having ordinary skill in the art would have to be motivated to keep the fixture body (10) and the cap (50) threadedly engaged when the screw (30) is driven into the expandable body. Doing so, however, goes completely against the teachings of Choung, which require the cap (50) to be removed prior to inserting the implant into the socket. (*Id.*) "It is improper to combine references where the references teach away from their combination." (MPEP § 2145(X)(D)(2), citation omitted.) Further, keeping the fixture body (10) and cap (50) threadedly engaged while rotating the screw (30) would render the implant unsatisfactory for its intended purpose because it would not work properly. Thus, a person having ordinary skill in the art would not have made such a modification. (*See* MPEP § 2143.01(V).)

Accordingly, claim 29, as well as claims 2-5, 7, and 12-17 which depend therefrom, distinguishes over Choung in view of McDevitt '252 and represents allowable subject matter.

Claim 44

Claim 44 depends from claim 29. Claim 29 distinguishes over Choung in view of McDevitt '252. As discussed above with respect to claim 29, Choung fails to disclose a shaft having a distal end and a proximal end that extends distally beyond a distal end of the distal tip member of the expandable

body. McDevitt '252 fails to remedy the deficiencies of Choung at least because a person having ordinary skill in the art would not modify Choung to include such a shaft. Including a shaft that extends distally beyond the fixture body (10) of Choung would interfere with the rotation of the screw (30), thereby rendering the implant unsatisfactory for its intended purpose. (*See* MPEP § 2143.01(V).)

Accordingly, at least because claim 44 depends from allowable base claim 29, which distinguishes over Choung in view of McDevitt '129, claim 44 represents allowable subject matter.

McDevitt '129

The Examiner rejects claim 38 pursuant to 35 U.S.C. § 103(a) as being obvious over McDevitt '129. Claim 38 depends from claim 29. The Examiner argues that McDevitt '129 discloses the claimed invention except a second bore formed in the expander pin and a second suture extending through the second bore. The Examiner argues, however, that including such recitations in the apparatus of McDevitt '129 would have been obvious because it would involve the mere duplication of essential working parts of a device.

At least because claim 38 depends from allowable base claim 29, which distinguishes over McDevitt '129 as discussed above, claim 38 represents allowable subject matter.

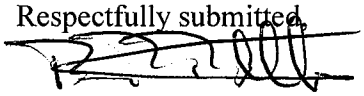
Double Patenting

The Examiner rejects claims 29-59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of the '506 patent and over claims 1-27 of McDevitt '252. Applicants reserve the right to submit a Terminal Disclaimer with respect to the term of either of these patents in the event that the Examiner maintains this rejection once patentable subject matter has been agreed upon.

Conclusion

All pending claims are believed to be in condition for allowance. If the Examiner believes that an interview would facilitate the resolution of any outstanding issues, he is kindly requested to contact the undersigned.

Respectfully submitted,



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